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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,876

03/11/2004

Arthur E. Uber III

IN/02-002.PCT.US.C

4883

21140

7590

11/05/2007

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/798,876	Applicant(s) UBER ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-143 is/are pending in the application.
- 4a) Of the above claim(s) 42-139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 and 140-143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/11/04, 12/14/04, 11/13/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, claims 1-41 and 140-143 in the reply filed on 8/28/07 is acknowledged. The traversal is on the ground(s) that the sole independent claim 42 of group II is very similar to the claim 1 of group I. Also, applicant asserts that groups I and II are connected in design and operation and lists the common design elements. This is not found persuasive because the invention of group II contains different design elements, specifically, an additional reservoir for accommodating a second liquid and a gas and a housing having at least one cell chamber while the system of group I does not contain these components. Therefore the inventions of group I and group II have different designs and modes of operation. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 42-139 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups II-XII, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/28/07.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-41 and 140-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (US 6,468,506B1) in view of Evans, III et al. (US 5,885,216) and further in view of Daum et al. (US 6,231,513) or Quay et al. (WO 96/40282).

5. Rossling et al. (US 6,468,506B1) discloses an apparatus for the production of gaseous microparticles for ultrasound diagnosis and the process for the production of gaseous microparticles (abstract; column 1, lines 8-9). The process for the production of gaseous microparticles involved pumping in gas into a surface-active substance solution and mixing with a stirring mechanism (column 2, lines 35-44). An alternative method for the production of gaseous microparticles involves spraying the solution via a nozzle into a column of gas into a column of gas (column 3, lines 25-29). The size of the resulting particles may be controlled by the nozzle size, shape, type as well as the working pressure and temperature in the column (column 3, lines 49-51). Figure 1 shows the apparatus for the production of gaseous microparticles. The apparatus includes a tank which may be filled with gas via a valve and line. The pump moves the solution from a tank via nozzle into a line, heat exchanger and column of gas, etc. Rossling et al. does not disclose a medium delivery system for direct injection into a patient or the production of microbubbles via ultrasound or the introduction of solid particles.

6. Evans, III et al. (US 5,885,216) discloses an apparatus for the injection of a contrast medium into a patient (column 3, lines 4-8). The apparatus comprises an electronic control system (column 5, lines 63-66) which provides for proper fluid flows

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according to the instructions of the operator and gets information on the contents of the bulk reservoirs (column 3, lines 57-59). Sensors are used to inform the controller system when the container is empty or for fluid assurance to prevent the problem of air embolism (column 3, lines 64+; column 4, lines 6-9). A metering pump (peristaltic pump) is used to draw contrast agent from the reservoir (column 4, lines 30-35), then a mixer is used to mix the fluids and a concentration monitor is used to provide feedback on the density, concentration, etc. (column 4, lines 44-62). A "sterilizing filter" is used to provide for sterile fluid coming out of the pump and to prevent migration of any bacteria from the patient into the pump and a spring-loaded ball valve is used to help prevent cross-contamination (column 4, lines 64+; column 5, lines 38-46).

7. Daum et al. (US 6,231,513) discloses the use of piezoelectric ultrasound for the preparation of gas-filled microbubbles used for ultrasound diagnosis. (column 4, lines 10-24). The apparatus includes passing a gas through the a porous matrix via microholes (column 3, lines 1-28).

8. Quay et al. (WO 96/40282) discloses the enhance production of gaseous microbubbles via the introduction of solid particles (p6, lines 7-12; p8, lines 7-25).

9. At the time of the invention it would be obvious to one ordinarily skilled in the art to utilize/try the microparticles prepared by the apparatus of Rossling et al. with the injector system of Evans, III et al. for direct administration of the contrast agent to a patient. Both disclosures are drawn to the same products, such contrast agents having the same utility, thus the results for combining would lead to predictable results. It would also be obvious to generate the microparticles via nucleation or piezoelectric

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ultrasound as they are all known techniques in the art. One would have a reasonable expectation of success for introducing a plurality of gases via inlets to vary/enhance the microbubble composition.

***Conclusion***


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
October 30, 2007

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER